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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/724,676      | 11/28/2000  | Zurit Levine         | 2786-0238P          | 9311             |

2292 7590 09/09/2004  
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EXAMINER

MARSCHER, ARDIN H

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1631

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/724,676

**Applicant(s)**

LEVINE ET AL.

**Examiner**

Ardin Marschel

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3 and 86-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 86-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 6/16/04, has been entered.

Applicants' arguments, filed 6/16/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **VAGUENESS AND INDEFINITENESS**

Claims 3 and 86-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3, lines 7-8 and line 27, cites the phrase "the CD-ROM" which is indicative of a specific CD-ROM. No antecedent basis for such a specific CD-ROM has been found prior to lines 7-8 or 27 to which the phrase "the CD-ROM" points to. This lack of clear antecedent basis for said phrase causes the claim to be vague and indefinite. Claims 88 and 90 also contain this unclarity specifically. Clarification via clearer claim

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wording is requested. Claims which depend directly or indirectly from claim 3 also contain this unclarity due to their dependence.

Claim 3, line 14, cites "said fragment" which lacks clear antecedent basis because no specific "said fragment" has been found in the claim. It is noted that "said fragment" is different from the plurality of fragments cited in line 13 in the phrase "fragments of (a) or (b)". Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 3 also contain this unclarity due to their dependence.

#### **LACK OF UTILITY REJECTION**

Claims 3 and 86-90 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

This rejection is reiterated and maintained as set forth in the previous office action, mailed 12/16/03, and applied equivalently to newly added claims 86-90 which only cite limited embodiments within instant claim 3 which are also subject to this rejection. Applicants argue that the elected sequences are related to kinases which have a well established utility. In response, the previous office action summarized the speculative and insufficient support for a utility based on sequence similarity. No other support for kinase character or even relatedness has been set forth either as filed or in arguments, filed 6/16/04. Thus, the well established utility of kinases does not support such a utility for the subject matter of instant claim 3. It is noted that applicants have not argued this basis for this lack of utility rejection which was set forth in the previous office

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action, mailed 12/16/03, inclusive of a series of publications to support the determination that sequence similarity is insufficient to determine the activity of a biomolecule such as a polypeptide. Thus, applicants have not argued the basis for this rejection and is therefore also non-persuasive.

### **LACK OF ENABLEMENT**

Claims 3 and 86-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Due to a lack of either an art recognized or alleged well established utility, the instant invention has been rejected due to also lacking the required combination of a specific, substantial, and credible utility.

This rejection is reiterated and maintained as set forth in the previous office action, mailed 12/16/03, and applied equivalently to newly added claims 86-90 which only cite limited embodiments within instant claim 3 which are also subject to this rejection. Applicants have not argued this rejection beyond the above arguments regarding lack of utility which are equally non-persuasive here.

### **SCOPE OF ENABLEMENT**

Claims 3 and 86-90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling (subject to the above noted lack of enablement) for SEQ ID NO: 70,493, does not reasonably provide enablement for homologues defined as having sequence additions, deletions, or replaced or chemically modified amino acids in the region that differs from the "original amino acid sequence". The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

This rejection is reiterated and maintained as set forth in the previous office action, mailed 12/16/03, and applied equivalently to newly added claims 86-90 which only cite limited embodiments within instant claim 3 which are also subject to this rejection. Applicants argue that instant claims 86, 88, and 90 are free of this rejection. In response, claims 86, 88, and 90 also include homologues due to their dependence from claim 3 which cites such homologues. Thus, applicants' argument is contrary to the factual content of the claims and therefore non-persuasive.

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### **LACK OF WRITTEN DESCRIPTION**

Claims 3 and 86-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is reiterated and maintained as set forth in the previous office action, mailed 12/16/03, and applied equivalently to newly added claims 86-90 which only cite limited embodiments within instant claim 3 which are also subject to this rejection. Applicants argue that instant claims 86, 88, and 90 are free of this rejection. In response, claims 86, 88, and 90 also include homologues due to their dependence from claim 3 which cites such homologues. Thus, applicants' argument is contrary to the factual content of the claims and therefore non-persuasive.

### **INFORMALITIES**

The disclosure is objected to because of the following informalities:

The claim status for claims 1-2 in the claims, filed 6/16/04, is improperly cited as "(cancel.))" which is improper due to being different as being an abbreviation compared to the proper status of "(Canceled)".

Appropriate correction is required.

No claim is allowed.

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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 3, 2004

*Ardin H. Marschel* 9/3/04  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER